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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,990	03/15/2004	Aaron B. Kantor	4220-99	3053

22442 7590 09/24/2007
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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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09/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/801,990		KANTOR ET AL.	
	Examiner		Art Unit	
	Jacob Cheu		1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 18-20, 22, 24, 25, 29 and 53-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 18-20, 22, 24-25, 29 and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment and Rule 131, 132 affidavits filed on 7/24/2007 have been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-15, 17, 21, 23, 26-28, 30-52 are cancelled.
2. Claims 16, 18-20, 22, 24-25, 29 and 53-58 are under examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16, 18-20, 22, 24-25, 29, 53-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 16, step (b), line 5, the term "hypothetical" protein DKFZp434P1818.1-human (fragment) is vague and indefinite. It is not clear what constitutes "hypothetical". No definition is given in the specification. Is it the "exact same" or "relating to"? Similarly, claims 20, 22 and 54 suffer the same problem. Also see below "Response to Applicant's Arguments". For clarity purpose, it is thus required applicant to submit SEQ ID No. for *each* of the recited marker (See below "*Response to Applicant's Arguments*") (emphasis added).

With respect to claim 16, step (b), line 7, "similar to KIAA1902" is vague and indefinite. It is not clear how "similar" this marker has to be. There is no clear metes and bounds and

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no definition of the degree of similarity. Similarly, claims 20, 22 and 55 suffer the same problem.

With respect to claim 16, step (b), line 7, "similar to KIAA1902 [Homo sapiens]" is vague and indefinite. The use of "[]" is confusing. This practice is for amending claim for deletion. It is not clear what exactly applicant intends to recite in the claim language. Similarly, the use of bracket :[]" for leucine-rich alpha-2-glycoprotein [Homo sapiens], gelsolin [Homo sapiens] and lumican [Homo sapiens] in the same claim and in claims 20, 22, 55-57 suffer the same problem. Applicant needs to clarify.

With respect to claim 16, step (b), "leucine-rich" alpha-2 glycoprotein is vague and indefinite. The specification has no definition what constitutes "rich", e.g. what percentage in the overall alpha-2 glycoprotein. Similarly, claims 20, 22 and 56 suffer the same problem.

Response to Applicant's Arguments

4. The rejections of claims 16, 19-20, 22, 24-25, 29, 54 and 55 rejected under 35 U.S.C. 112, first paragraph are withdrawn because applicant provides evidence (See affidavits) from NCBI gene bank with its sequence related to the "hypothetical protein DKFZp434P1818.1" and "similar to KIAA 1902 protein". However, with respect to the clarity of the claim language (35 USC 112, second paragraph), the rejections maintain.

Amino Acid Sequence

It is apparent that the amino acid sequences disclosed in GenBank with Accession No. from Tables 1-4 are required for making and using the claimed invention. However, applicant has not provided the sequence. The amino acid sequence is considered essential subject matter to the instant application and the claimed invention. Applicant is

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thus required to provide the SEQ ID No. in the claim for each of the recited marker for clarity (emphasis added). It is noted that applicant had provided affidavits disclosing all the sequence of the marker corresponded to its accession number listed from the Table.

The specification discloses subject matter into this application by mentioning GenBank Accession No. is improper because an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, see MPEP 608.01(p). "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Applicant is also required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973)(emphasis added).

5. The rejections of claims 16, 24-25 and 58 under 35 USC 103 (a) as unpatentable over Winchester et al. in view of Dwek et al. are withdrawn because Winchester et al. do not explicitly teach that lumican can be a marker for RA compared to a healthy control, albeit the level of lumican is higher in the RA patients, nevertheless Winchester et al. attribute to the combination factors other than the RA alone. No explicit or suggestion about using lumican as a marker to screen RA patients.

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6. The rejections of claims 16, 18-19, 53 under 35 U.S.C. 103(a) as being unpatentable by Chard et al.) in view of Dwek et al. are withdrawn because applicant cancelled the ACT marker.

7. Similarly the rejection of claim 20 under 35 U.S.C. 103(a) as being unpatentable over as Chard et al. in view of Dwek et al., and further in view of Winchester et al. is withdrawn because the ACT marker is cancelled.

Conclusion

Allowable Subject Matter

8. Claims 16, 18-20, 22, 24-25, 29 and 53-58 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

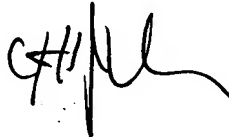
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

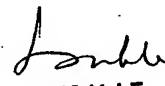
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner



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September 13, 2007


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